K111068 1/2

DEC 3 0 2011

skeletal dynamics

510(k) Summary of Safety and Effectiveness
Skeletal Dynamics Stablyx CMC Arthroplasty Implant Set

April 14, 2011

Submitter:
Skeletal Dynamics, LLC
8905 SW 87 Avenue
Suite 102
Miami, FL 33176
Tel: (305) 596-7585
Fax: (305) 596-7591
Contact: Ana M. Escagedo, Vice President
Email: aescagedo@skeletaldynamics.com

Establishment Registration Number: 3006742481

Trade Name, Common Name, Classification:

Trade Name	Stablyx CMC Arthroplasty Implant Set
Common Name	Prosthesis, wrist, carpal trapezium
Classification	21 CFR §888.3770
Product Code	KYI
Class	Class II

Predicate Devices:
Ascension, PyroCarbon Saddle CMC (K061451)
BioPro Modular Thumb Implant (K052596)

Description of the Device:
The Stablyx CMC Arthroplasty System is a hemi monoblock prosthesis for replacement of the first metacarpal carpometacarpal (CMC) joint. The single piece prosthesis has a highly polished, saddle shaped (toroidal) articular surface which mirrors the normal anatomy of the base of the first metacarpal. The saddle surface of the Stablyx CMC prosthesis articulates against the saddle surface of the trapezium, allowing for flexion-extension, abduction-adduction and opposition motions.

The prosthesis is available in five sizes, and is made of Cobalt Chrome (CoCr) with a Titanium Plasma Spray (TPS) coated stem which may assist in biological fixation. The stem is intended to press fit into the medullary canal. Each prosthesis is packaged and provided sterile.

The Stablyx CMC Arthroplasty System is comprised of:

- Multiple sized hemi joint prosthesis
- System specific instrumentation

Intended Use:
The Skeletal Dynamics Stablyx CMC Arthroplasty Implant set is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation or bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion. This implant is intended for uncemented, press fit use.

Summary of Technological Characteristics / Substantial Equivalence:
The substantial equivalence of the Skeletal Dynamics Stablyx CMC Arthrodesis Implant Set to the predicate devices is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging, and does not present any new issues of safety or effectiveness.

Performance Testing:
Engineering analysis and cadaveric testing demonstrated that the Stablyx CMC Arthrodesis Implant Set is substantially equivalent to devices currently marketed. Therefore, the subject device is as safe and effective as legally marketed predicate devices.

Conclusion:
The Skeletal Dynamics Stablyx CMC Arthrodesis Implant Set is substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC 3 0 2011

Skeletal Dynamics, Inc.
% Ms. Ana Escagedo
8905 SW 87th Avenue
Suite 201
Miami, Florida 33176

Re: K111068
Trade/Device Name: Stablyx CMC Arthroplasty System
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: II
Product Code: KYI
Dated: December 10, 2011
Received: December 12, 2011

Dear Ms. Escagedo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111068

Device Name: Stablyx CMC Arthroplasty Implant Set

Indications For Use:
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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111068